with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications.* Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations.* Administer only by deep intramuscular injection in the lumbar muscles (L_3-L_5). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Sydrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995]

§ 522.1367 Meloxicam.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 68724, Dec. 10, 2003, as amended at 69 FR 69523, Nov. 30, 2004]

§ 522.1372 Mepivacaine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 20 milligrams of mepivacaine hydrochloride.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 5349, Jan. 28, 1977, as amended at 42 FR 36995, July 19, 1977; 55 FR 23076, June 6, 1990; 69 FR 69523, Nov. 30, 2004]

§522.1380 Methocarbamol injection.

(a) *Specifications.* The product is a sterile, pyrogen-free solution, each milliliter containing 100 milligrams of methocarbamol, 0.5 milliliter of polyethylene glycol 300, and water for injection q.s. Its pH is 3.5 to 6.0.

(b) *Sponsor.* See No. 000856 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* 20 milligrams per pound of body weight for moderate conditions, 25 to 100 milligrams per pound of body weight for severe conditions (tetanus and strychnine poisoning), total cumulative dose not to exceed 150 milligrams per pound of body weight.

(ii) *Horses.* 2 to 10 milligrams per pound of body weight for moderate conditions, 10 to 25 milligrams per pound of body weight for severe conditions (tetanus), additional amounts may be needed to relieve residual effects and to prevent recurrence of symptoms.

(2) *Indications for use.* As an adjunct for treating acute inflammatory and traumatic conditions of the skeletal muscles and to reduce muscular spasms.

(3) *Limitations.* For intravenous use only. For dogs, administer rapidly half the estimated dose, pause until the animal starts to relax, then continue administration to effect. For horses, administer rapidly to effect. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 79758, Dec. 2, 1980, as amended at 46 FR 18964, Mar. 27, 1981; 67 FR 67521, Nov. 6, 2002]

§522.1410 Sterile methylprednisolone acetate suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains 20 or 40 milligrams of methylprednisolone acetate.[1]

(b) *Sponsors.* See Nos. 000009 and 000010 in §510.600(c) of this chapter.

(c) *Special considerations.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone acetate, as with other corticoids, is contraindicated in animals with arrested tuberculosis, peptic ulcer, and Cushing's syndrome. The presence of active tuberculosis, diabetes mellitus, osteoporosis, renal insufficiency, predisposition to thrombophlebitis, hypertension, or congestive heart failure necessitates carefully controlled use of corticosteroids. Intrasynovial, intratendinous, or other injections of corticosteroids for local effect are contraindicated in the presence of acute infectious conditions. Exacerbation of pain, further loss of joint motion, with fever and malaise following injection may indicate that the condition has become septic. Appropriate antibacterial therapy should be instituted immediately.

(d) *Conditions of use*—(1) *Amount*—(i) *Intramuscular.* Dosage may be repeated when necessary, as follows: dogs—2 to 40 milligrams (up to 120 milligrams in extremely large breeds or dogs with severe involvement); cats—10 to 20 milligrams; horses—200 milligrams. [1]

(ii) *Intrasynovial.* Dosage may be repeated when necessary, as follows: horses—40 to 240 milligrams; dogs—up to 20 milligrams.[1]

(2) *Indications for use.* Treatment of inflammation and related disorders in dogs, cats, and horses;[1] treatment of allergic and dermatologic disorders in dogs and cats; and as supportive therapy to antibacterial treatment of severe infections in dogs and cats.

(3) *Limitations.* Not for use in horses intended for food. Not for human use. Federal law restricts this drug to use

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.